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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/092,640 | 03/05/2002 | James D. Marks | 407T-897221US | 1369 |

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

| EXAMINER | |
|---|---|
| YAEN, CHRISTOPHER H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/092,640 | MARKS ET AL. | |
| | Examiner | Art Unit | |
| | Christopher H Yaen | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 March 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-28,34-39,41 and 45-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21-28,34-39,41 and 45-50* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 21-28,41, and 45-47, drawn to a nucleic acid molecule encoding a human C6 antibody, a cell comprising the recombinant nucleic acid that encodes the human C6 antibody, and an expression cassette comprising the nucleic acid that encodes the human C6 antibody classified in class 536, subclass 23.1.

II. Claims 34-37, drawn to a method of making a C6 antibody by panning and isolating phage from a library, classified in class 435, subclass 6, for example.

III. Claim 38, drawn to a method of impairing the growth of a tumor cell comprising the contacting with a chimeric molecule comprising a cytotoxin attached to a C6 antibody, classified in class 424, subclass 178.1 for example.

IV. Claim 39, drawn to a method of detecting tumor cells comprising the contacting of tumor cells with a chimeric molecule comprising a label attached to a C6 antibody, classified in class 435, subclass 5, for example.

V. Claims 48-50, drawn to a method of inducing the production of a polypeptide comprising the introduction, expression of the expression cassette of group I, and isolation of polypeptide classified in class 435, subclass 69.7, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The nucleic acid encoding the C6 antibody (group I), the method of impairing the growth of a tumor cell comprising the contacting of a cell with a chimeric antibody (group III), and the method of detecting tumor cells comprising the contacting of tumor cells with a labeled antibody (group IV) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for treating tumor cells and detecting tumor cells differ significantly from each other. For treating tumor cells, a chimeric antibody conjugated to a cytotoxin is required. For the method of detecting tumor cells, a labeled antibody is required. All of these methods are drawn to methods of using an antibody, none of which require the nucleic acid, host cells or expression vector of group I. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I, III, and IV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I, III, and IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I, III, and IV together.

3. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made through other means such as through hydridoma technology.

Searching the inventions of groups I and II together would impose serious search burden. The inventions of groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides, host cells and vectors and the method of making the antibody using phage libraries for the isolation of a protein/antibody are not coextensive. Group I encompasses molecules which are claimed in terms of nucleic acid sequences, which are not required for the search of Group II. In contrast, the search for group II would require a text search for the method of using phage libraries for the isolation of an antibody that binds to the c-erbB-2 antigen. Prior art which teaches a polynucleotide sequence that encodes the human C6 antibody would not necessarily be applicable to the method of making the C6 antibody through the phage library screening. Moreover, even if the polynucleotide product were known, the method of making the antibody using phage libraries may be novel and unobvious in view of the preamble or active steps.

4. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of making the protein/antibody of group V can be accomplished by using hybridoma technology.

Searching the inventions of groups I and V together would impose serious search burden. The inventions of groups I and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides, host cells and vectors and the method of using a polynucleotide for the production of a protein/antibody are not coextensive. Group I encompasses molecules which are claimed in terms of sequence identification numbers, which are not required for the search of Group V. In contrast, the search for group V would require a text search for the method of using the nucleic acid molecules identified by sequence identifiers to make and antibody. Prior art which teaches a polynucleotide identical to the elected sequence would not necessarily be applicable to the method of using the elected sequence. Moreover, even if the polynucleotide product were known, the method of making the protein/antibody using the nucleic acid molecule may be novel and unobvious in view of the preamble or active steps.

5. Inventions II, III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The methods of making the C6 antibody, impairing and detecting tumor cells

with the C6 antibody and the method of inducing the production of the polypeptide with an expression cassette of group I are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for performing each of the claimed method steps are different. For example, the method of making the antibody differs from the other methods because it requires the contacting and panning of a phage library to isolate a phage the binds to a specific antigen. The method of impairing the growth of a tumor comprises the contacting of a tumor with a conjugate that comprises a toxin attached to a C6 antibody. The method of detecting tumor cells comprises the contacting of a tumor cell with a conjugate that comprises a label attached to C6 antibody. And finally, the method of inducing the production of a polypeptide comprises the cloning, expression, and isolation of a polypeptide in a host cell. Therefore, each method is divergent in materials and steps. For these reasons the Inventions II, III, IV, and V are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups II, III, IV, and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups II, III, IV, and V together.

6. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group

requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
February 17, 2005